

## **Invent Medic Sweden AB announces that a preliminary analysis of the clinical multicenter study shows significant positive results**

**Invent Medic Sweden AB ("Invent Medic") announces herewith that a preliminary analysis of the data from the clinical multicenter study on the company's product shows that using the TVS provides significant reduction of urinary leakage. This means that the study reached its primary endpoint. The final results from the study will be communicated after the final report has been presented to the company.**

In the clinical multicenter study, the amount of urinary leakage was evaluated between a control group and a treatment group that used the company's product TVS. Invent Medic has received initial calculations that shows that the study has reached its primary endpoint, thus the TVS group show significant reductions in urinary leakage. No serious injuries or side effects have been reported in connection with use of TVS. A final report with results from the study will be presented to the company and thereafter the company will complete all documentation necessary for the Technical file (a compilation file about the product) and present it to the Notified Body, RISE, for review. When RISE has reviewed the technical file, a meeting will take place between the company and RISE where the documentation is reviewed at the company premises. The company has no influence on the timeline for the CE-process after delivery of the documentation, but with that said it is assumed that TVS can obtain its CE mark in Q2/2018.

### **Karin Bryder, CEO of Invent Medic, comments:**

*"These positive initial results from the clinical investigation and the study as a whole, strengthens the confidence and inspires continued work towards the CE process and launch of TVS. The TVS will be able to make a big difference for women who are affected by stress urinary incontinence. Our CRO will continue to analyse data as planned and the results will be compiled in a clinical report. These data will be used as part of the documentation in the technical file that our notified Body reviews in towards a CE mark."*

The clinical study was conducted at four study clinics in Sweden and was coordinated by senior physician Aino Fianu Jonasson at Karolinska University Hospital in Stockholm. Total 97 women were included in the study.

### **For more information please contact**

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This information is information that Invent Medic Sweden AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 15 February 2018.

***Invent Medic Sweden AB***, Company registration number 556682-1046, has developed a medical device for non-surgical relief of female stress urinary incontinence. The inventors behind the product, Jan Clarén and Lars-Olof Henriksson, have been involved in the development and performance of the surgical method TVT, which is now known as the Golden Standard for surgical treatment of female stress incontinence. The product is based on the same scientific basis and has similar mechanism of action as the surgical method but is based on a non-surgical support and is designed so that the woman can use the product when needed. This product has the potential to satisfy a major medical need and could thus have a significant market value. Invent Medic's vision is to offer new and innovative medical devices and treatment methods to women with the goal of improving their health and quality of life. The offer shall include safe, effective and safe products and treatment methods that should be easy to use and which will provide health economic benefits to society. Invent Medic Sweden AB is listed on Aktietorget. Ticker is IMS and the share's ISIN code is SE0007603402. For more information see [www.inventmedic.com](http://www.inventmedic.com) and [www.aktietorget.se](http://www.aktietorget.se)